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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,437	12/17/2001	Stephen A. Johnston	5171-00041	2358
<div>7590 06/29/2007</div> <div>ANDRUS, SCEALES, STARKE &amp; SAWALL, LLP</div> <div>Suite 1100</div> <div>100 East Wisconsin Avenue</div> <div>Milwaukee, WI 53202</div>				
			EXAMINER	
			FORD, VANESSA L	
			ART UNIT	PAPER NUMBER
			1645	
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			06/29/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/023,437	<b>Applicant(s)</b> JOHNSTON ET AL.	
	<b>Examiner</b> Vanessa L. Ford	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 92-95 and 104-121 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 92-95 and 104-121 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### FINAL ACTION

1. This Action is responsive to Applicant's amendment and remarks filed April 18, 2007. Claims 1-91 and 96-103 have been cancelled. Claims 92-95 and 104-121 are under examination.

### ***Rejection Withdrawn***

2. In view Applicant's amendment and remarks the rejection of claim 74 under 35 U.S.C. 112 second paragraph, page 10, paragraph of the previous Office action is withdrawn.

### ***Rejection Maintained***

The rejection is reiterated below:

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 92-95 and 104-121 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are direct to a method of immunizing an animal comprising the steps administering a *Chlamydia psittaci* antigen to an animal in an amount effective to induce an immune response against *Chlamydia psittaci* wherein the *Chlamydia psittaci* antigen comprise the amino acid sequence as set forth as SEQ ID NO:7, SEQ ID NO:9 SEQ ID NO:11 and SEQ ID NO:13 (sequences examined with regard to the claimed invention).

The instant specification teaches that SEQ ID NO: 7 (CP4#1) is a polypeptide translation corresponding to SEQ ID NO:6 homolog to *Chlamydia pneumoniae* DNA POL III Gamma and TAU subunits. The specification teaches that SEQ ID NO: 9 (CP4#1) is a polypeptide translation corresponding to SEQ ID NO:8 homolog to *Chlamydia pneumoniae* DNA POL III Gamma and TAU subunits. SEQ ID NO: 11 (CP4#2) is a polypeptide translation corresponding to SEQ ID NO:10 homolog to *Chlamydia pneumoniae* Glu-tRNA Gln Anido-transferase (C subunit) (gatC gene) and SEQ ID NO:13 is (CP4#2) is a polypeptide translation corresponding to SEQ ID NO:12

Art Unit: 1645

homolog to *Chlamydia pneumoniae* Glu-tRNA Gln Anido-transferase (C subunit) (gatC gene).

The instant specification discloses in Examples 5-12 experimental examples using *Chlamydia* nucleic acid molecules and polypeptides used to immunize animals. The specification refers Figures 4- 8 which disclose the data from the various experimental examples. Regarding figure 5, which are the results of protection assays of testing individual gene fragments in found 4 (page 15). The specification teaches that protection was scored as lung weight relative to the average of the vaccinate, maximum protection, positive control (vaccinated =1) and the non-vaccinated, challenged, maximum disease, negative control (challenged=0). It is unclear as to what Applicant intends by the data presented in Figure 5. The instant specification presents data in terms of maximum protection. Applicant does not present an unvaccinated control. Thus, one of skill in the art cannot interpret Applicant's data as set forth regarding protection assays with data from an unvaccinated control. It is unclear as to what the data present in figure 5 actually discloses. The skilled artisan cannot draw in conclusive evidence from the data presented in the instant specification.

The structure of the elected sequences (SEQ ID Nos 7 and 9) have 48.4% and 64.4% sequence identity, respectively with the DNA polymerase III gamma and tau family of polypeptides from *Chlamydia pneumoniae*. See the sequence alignments below:

**SEQ ID : 7, DNA polymerase III gamma and tau [imported] – Chlamydia pneumoniae (strain J138)**  
 Query Match 48.4%; Score 369.5; DB 2; Length 442;  
 Best Local Similarity 56.2%; Pred. No. 2.6e-28;  
 Matches 81; Conservative 21; Mismatches 33; Indels 9; Gaps 3;

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Qy      3 IRTQKYAEALLPVTTAINSGVAPITFLHDLTVFYRDVLLNKDQGNSPLSAIAMHYSSECL 62
      | : || || || :||||:|||||:||||:| || | : | :|
Db      260 ILQRDYATALGIVTDFLNSGVAPVTFHDLTLFYRNLLLT----NSTTSKFSSQYKTEQL 315

Qy      63 LEIIDFLGEAAKHLQQTIFEKTFLETVIIHLIRICQRPSLETLFSQLKTSTFDTVRNVPQ 122
      |||||:|||| |||:|||||:|||| || | | :| :| :
Db      316 LEIIDFLGESAKHLQNTIFEQTFLETVIIIRIYQRPVLSSELISIKSRQFEGLRNIKE 375

Qy      123 ---QQEPSKPSIQPEKHYQDQSFL 143
      | : || || :|||
Db      376 PTLTQQVSAP--QPQPTYKEQSFL 397
  
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Art Unit: 1645

**SEQ ID NO:9:** DNA polymerase III gamma and tau - *Chlamydia pneumoniae* (strains CWL029 and AR39)

Query Match 64.4%; Score 1443; DB 2; Length 442;  
 Best Local Similarity 66.8%; Pred. No. 1.9e-93;  
 Matches 298; Conservative 48; Mismatches 88; Indels 12; Gaps 4;

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Qy      1 MTSATYQVSSRKYPQTFAEMLGQDAVVTVLKNALQFQRVAHAYLFSGIRGTGKTTLARI 60
      || ||||||| | | | | | || ||||| | | |||||||||
Db      1 MTLQPYQASSRKYPQIFREILGQSSVAVLKNALVFNRAAHAYLFSGIRGTGKTTLARI 60

Qy     61 FAKALNCKELTPEHEPCNQCCVCKEISSGTSLDVIEIDGASHRGIEDIRQINETVLFTPA 120
      ||||| | | | | | ||||| | | |||||||||
Db     61 LAKALNCVHLSEDGEPCNQCFSCKEIASGSSLDVLEIDGASHRGIEDIRQINETVLFTPV 120

Qy    121 KSQYKIYIIDEVHMLTKEAFNSLLKTLLEPPSHVKFFLATTENYKIPSTILSRCQKMHLK 180
      ||||| | | | | | ||||| | | ||||| | | |||||
Db    121 KAKFKIYIIDEVHMLTKEAFNALLKTLLEPPQHVKFFATTEIHKIPGTILSRCQKMHLQ 180

Qy    181 RIPETMIVDKLASISQAGGIETSREALLPIARAAQGSLRDAESLYDYVIGLFPTSLSPEL 240
      |||| | | | | | || | | | ||||||||| || |||
Db    181 RIPEKTILEKLSLMAQDDHIEASQEALAPIARAAQGSLRDAESLYDYVISLFPKSLSPDT 240

Qy    241 VADALGLLSQDTLATLSECIRTQKYAEALLPVTTAINSGVAPITFLHDLTVFYRDVLLNK 300
      || || | | | | | | | | | | ||||| | | |||||
Db    241 VAQALGFASQDSLRRLDNLALQRDYATALGIVTDFLNSGVAPVTLHDLTLFYRNLLLT- 299

Qy    301 DQGNSPLSAIAMHYSSECLLEIIDFLGEAAKHLQQTIFEKTFLETVIIIHLIRICQRPSLE 360
      || | | | | | | | | | | ||||| | | |||||
Db    300 ---NSTTSKFSSQYKTEQLLEIIDFLGESAKHLQNTIFEQTFLETVIIIIRIYQRPVLS 356

Qy    361 TLFSQLKTSTFDTVRNVQP---QQEPSKPSIQPEKHYQDQSFL---TSPSPTPKVQHQKE 414
      || | | | | | | | | | | || | | | | | |
Db    357 ELISSIKSRQFEGLRNIKEPTLTQQVSAP--QPQPTYKEQSFEKKNQPAEGKIISVEV 414

Qy    415 ASPSLVGSATIDTLLQFAVVEFSGIL 440
      | | | | | | | | | |
Db    415 KSSASIKSAAVDLTLLQFAVVEFSGIL 440
  
```

The structure of the elected sequences (SEQ ID Nos 11 and 13) have 46.4% and 62.8% sequence identity, respectively with the family glu-tRNA amidotransferase C chain of polypeptides from *Chlamydia pneumoniae*. See the sequence alignments below:

**SEQ ID NO: 11, C;**Superfamily: probable glu-tRNA amidotransferase C chain

Query Match 46.4%; Score 91; DB 2; Length 100;  
 Best Local Similarity 35.9%; Pred. No. 0.00018;  
 Matches 14; Conservative 14; Mismatches 11; Indels 0; Gaps 0;

Qy 3 IQEYESSLNEVIKTMASIAMDVTDVVIEVGLSHVISPE 41

Art Unit: 1645

Db 27 VEEFVTSMNDVIALMQEVIADISDIILEATVHHFVGPE 65

C;Superfamily: probable glu-tRNA amidotransferase C chain

SEQ ID NO: 13, Query Match 62.8%; Score 301; DB 2; Length 100;  
Best Local Similarity 56.0%; Pred. No. 5.8e-21;  
Matches 56; Conservative 24; Mismatches 20; Indels 0; Gaps 0;

Qy 1 MTQPYVTREDIILLAKSSALELSEEFIQEYESSLNEVIKMAASIAMDVTDVVIEVGLSH 60

Db 1 MTESYVNKEEIIISLAKNAALELEDAHVEEFVTSMNDVIALMQEVIADISDIILEATVHH 60

Qy 61 VISPEDLREDIVASSFSREEFLTNPESLGGLVKVPTVIK 100

Db 61 FVGPEDLREDMVTSDFTQEEFLSNVPVSLGGLVKVPTVIK 100

The state of the art regarding DNA Pol III gamma and Tau subunits and amind-transferase (C subunit) (gene C gene) are described below:

McHenry (*Molecular Microbiology* 2003, 49(5), 1157-1165) teach that genome sequencing studies have revealed that low GC content gram-positive bacteria have two polymerases. McHenry teaches that one type is prototypical gram-positive bacterial PolC which is characterized by a catalytic subunit with proofreading exonuclease activity and the second is polymerase is homologous to the  $\alpha$  subunit of *E. coli* Pol III (DnaE). Genetic analysis indicate that both polymerases are essential for viability (pages 1162-1163). Therefore, the skilled artisan would conclude from the review of the cited art that this polypeptide is not an outer-membrane protein and internal to *Chlamydia psittaci* and is involved in transcription.

Curnow et al (*Proc. Natl. Acad. Sci.*, Vol. 94, October 1997, p. 11819-11826) teach that three genes gatC, gatA and gatB constitute the transcriptional unit of gram-positive bacteria (see the Abstract). Racznik et al (*The Journal of Biological Chemistry*) teach that GatC is the most divergent subunit for which no function can be suggested by homology searches (page 45867). Racznik et al teach that it was proposed that GatC is required for proper expression or folding of the GatA subunit (page 45867). Therefore, the skilled artisan would conclude from the review of the cited art that this polypeptide is not an outer-membrane protein and internal to *Chlamydia psittaci* and is involved in transcription.

The specification has failed to teach or disclose how the data in figure 5 correlates to protection assays. Thus, one skilled in the art cannot conclude that there is a correlation between protective immunity and the claimed method of immunizing animals using the claimed polypeptides as set forth in SEQ ID Nos: 7, 9, 11 and 13 since there is no unvaccinated control data presented and the skilled artisan cannot drawn in conclusive evidence from the data presented in the instant specification.

The prior art as cited above has taught that DNA pol III gamma and tau as well as gatC are enzymes which are involved in transcription. These proteins are not known in the art as being potential antigens to protect against *Chlamydia* or any other bacterial infections. In fact, the art teaches that the function of GatC is unknown.

Art Unit: 1645

Based on the instant specification the skilled artisan would not reasonably conclude that the claimed method is enabled. As, state above, it is unclear how Applicant interprets the data present in for example, Figure 5, since no unvaccinated control is present and the data is disclosed in the terms of maximum protection.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with regard to data present which correlates to protection assays in which the claimed method has been practiced, 3) there are no working examples are not specific to particular antigen used in the claimed method of immunizing an animal, 4) the relative skill of those in the art is commonly recognized as quite high (post - doctoral level), and 5) the state of the art in the field to which the invention pertains is recognized in the art as evidenced by the cited prior art.

In view of all of the above, in view of the lack of guidance provided in the specification, it is determined that it would require undue experimentation to make and use the claimed invention. Applicant is asked to place on the record, what they intend by the data present in figure 5.

#### Applicant's Arguments

Applicant urges that the filed Declaration submitted by Dr. Bernhard Kaltenboeck declares that Figure 5 is clear and sets forth what Applicant intends data presented in Figure 5. Applicant urges the clarification provided by the declaration submitted by Dr. Bernhard Kaltenboeck with respect to Figure 5 and the data presented in Figure 5 clearly shows how the sequence ids correlate to protection.

Examiner's Response to Applicant's Arguments

The declaration submitted by Dr. Bernhard Kaltenboeck under 37 CFR 1.132 filed April 18, 2007 is insufficient to overcome the rejection of claims 92-95 and 104-121 as set forth in the last Office action.

While Applicants have provided a great description as to how the experimental assays were performed (in the form of a declaration) to arrive at the data presented in Figure 5, the declaration presented by Applicants fails to provide a correlation between the data presented in the specification and the SEQ ID Nos. recited in the claims. For example, the claims are directed to a method of immunizing an animal comprising the steps of administering a *Chlamydia psittaci* antigen to an animal to induce an immune response against *Chlamydia psittaci* wherein the *Chlamydia psittaci* antigens comprise SEQ ID Nos. 7, 9, 11 or 13 (the elected sequences examined). The instant specification teaches that SEQ ID NO: 7 is CP4#1, a polypeptide translation corresponding to SEQ ID NO:5, homolog to *Chlamydia pneumoniae* DNA Pol III Gamma and Tau subunits (dnaX2 gene), SEQ ID NO: 9 is CP4#1, a polypeptide translation corresponding to SEQ ID NO:8, homolog to *Chlamydia pneumoniae* DNA Pol III Gamma and Tau subunits (dnaX2 gene), SEQ ID NO: 11 is CP4#2, polypeptide translation corresponding to SEQ ID NO:10 homolog to *Chlamydia pneumoniae* Glu-tRNA Gln Amido-transferase (c subunit) (gatC gene) and SEQ ID NO: 13 is CP4#2, polypeptide translation corresponding to SEQ ID NO:12 homolog to *Chlamydia pneumoniae* Glu-tRNA Gln Amido-transferase (c subunit) (gatC gene). See page 75 of



the specification). Figure 5, discloses single gene fragments and designates these fragments as 1-14. It is unclear as to which gene fragments (designated as 1-14) on Figure 5 corresponds to which SEQ ID NO: recited in the claims. Further, it is unclear as to how to distinguish the CP4#s and the SEQ ID NOs recited on page 75 of the specification since SEQ ID NO:7 and SEQ ID NO:9 are both designated CP4#1 and likewise for SEQ ID Nos: 11 and 13.

Taken together, it is unclear as to which antigens (SEQ ID Nos) were used to generate the data presented in Figure 5 of the instant specification. Therefore, it is unclear as if the antigens used in the experimental examples actually correlate to the data presented in Figure 5 or more importantly it is unclear as to whether the antigens recited in the claimed method were used in the experimental examples.

In view of all of the above, the enablement rejection under 35 U.S.C. 112, first paragraph is maintained and the Office requests a detail explanation as to how the data presented in the specification and the declaration correlate with the *Chlamydia* antigens (SEQ ID Nos:7, 9, 11 and 13) that are recited in the claimed method. This explanation is needed to evaluate the enablement requirement as set forth under U.S.C. 112, first paragraph which requires knowledge as to how the skilled artisan would make and used the claimed invention.

***Status of Claims***

4. No claims are allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1645


### **Conclusion**

6. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Vanessa L. Ford  
Biotechnology Patent Examiner  
June 18, 2007

  
JEFFREY SIEW  
SUPERVISORY PATENT EXAMINER